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|  | APPLICATION NO. | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|-----------------|----------------|----------------------|--------------------------|------------------|
|  | 10/076,369      | 02/19/2002     | Henry William Lupton | Q68587                   | 1502             |
|  | 75              | 590 04/12/2006 | ·                    | EXAMINER                 |                  |
| SUGHRUE MION, PLLC<br>2100 Pennsylvania Avenue, NW |                 |                |                      | HO, UYEN T               |                  |
|  |                 | C 20037-3213   |                      | ART UNIT                 | PAPER NUMBER     |
|  |                 |                |                      | 3731                     |                  |
|  |                 |                |                      | DATE MAIL ED. 04/12/2004 | •                |

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | A 12 - 42 N -   | A 41 44 3                   |  |  |  |  |  |
|--|---|-----------------------------|--|--|--|--|--|
|  | Application No.   | Applicant(s)                |  |  |  |  |  |
| Office Action Summany  | 10/076,369  | LUPTON, HENRY WILLIAM       |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                    |  |  |  |  |  |
|  | (Jackie) Tan-Uyen T. Ho   | 3731                        |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence address       |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                             |  |  |  |  |  |
| Status   |   |                             |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 22 M  | <u>.                                    </u>                              |                             |  |  |  |  |  |
|  | action is non-final.  |                             |  |  |  |  |  |
| <i>'</i>   | <del>, _</del>  |                             |  |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |                             |  |  |  |  |  |
| ·  | n pario gaayio, 1000 o.b. 11, 10  |                             |  |  |  |  |  |
| Disposition of Claims  |   |                             |  |  |  |  |  |
| )⊠ Claim(s) <u>1-5 and 7</u> is/are pending in the application.  |   |                             |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |                             |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                             |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-5 and 7</u> is/are rejected.   |   |                             |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                             |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | r election requirement.   | ·                           |  |  |  |  |  |
| Application Papers   | •   |                             |  |  |  |  |  |
| 9) The specification is objected to by the Examine   | r.  |                             |  |  |  |  |  |
| 0) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |                             |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                             |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                             |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                             |  |  |  |  |  |
| ,  |   |                             |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                             |  |  |  |  |  |
| a) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:   |   |                             |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |                             |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |                             |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                             |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                             |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                             |  |  |  |  |  |
|  | •   |                             |  |  |  |  |  |
|  |   |                             |  |  |  |  |  |
| Attachment(s)  |   |                             |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |                             |  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SR/08)   | Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) |                             |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | 6) Other:   | atom application (1 10-102) |  |  |  |  |  |
|  |   |                             |  |  |  |  |  |

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#### **DETAILED ACTION**

#### Response to Arguments

- 1. Applicant's arguments and amendment filed 2/8/06 have been considered but are most in view of the new ground(s) of rejection.
- 2. Applicant's election without traverse of species I in the reply filed on 2/10/05 is acknowledged. After a careful reconsideration of the is application, other species are considered as obvious variants of species I. Therefore, Election/Restrictions mailed on 12/15/04 is withdrawn.

### Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1-5, 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification fails to support the newly added limitation "wherein the corrugated section has a flexibility to that of another section of the hollow body". The original specification discloses the corrugated section increasing the flexibility of the tubular body (paragraph 20).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that 5. form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Dusbabek et al. (5,968,069).

Regarding to claims 1, 2 and 7, Dusbabek et al. disclose a catheter having an elongate body (212), the body (212) defined by walls, an outer wall (216) and an inner wall (212 inside the outer wall 216) wherein the section having the outer and inner wall is corrugated at least at the outer wall section (216) of the tubular member and includes a plurality of ribs (fig. 30-33); a proximal region of the tubular body (212) is smooth; a stent (218) and a support region (214) is formed over the corrugated section. Dusbabek et al. disclose the outer wall 216 being made from flexible material and the solid inner sheath (212, col. 20, lines 28-29). Examiner's position is that the corrugated section including inner (wall of tubular 212) and outer walls (216) has a flexibility to that of another section of the hollow body since the wall section (212) being made from the same material from other section of the hollow body and the outer walls (216) is more flexible than the inner body, it won't affect the flexibility of the section (212) at the corrugated section.

Regarding to claims 1, 2 and 7, Dusbabek et al. also discloses a catheter having an elongate body (372, fig. 43-45), the body being a tubular member and the tubular member having at least one corrugated section (354) in the distal region, a support region (358) formed over the corrugated section and a stent (360). Corrugated section has flexibility to that of another section of the hollow body because they all are made from the same material.

#### Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. (6,607,551) in view of Dusbabek et al. (5,968.069). Sullivan et al. all the limitations of the claims except for the presence of an inflatable member, slots and that the body is not hollow as claimed.

Regarding to the hollow body, it is well known in the art to have a delivery catheter system including inner member having guidewire lumen in order to accommodate a guidewire therethrough for guiding the delivery system to a target site.

Regarding to the balloon disposed about the corrugated section, Dusbabek et al. disclose a balloon disposed about the corrugated section for delivering and expanding non-self expanding stent as well as self-expanding stent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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employ a balloon system as disclosed by Dusbabek et al. into Sullivan et al.'s delivery system in order to deliver a non-self-expanding stent as well as self-expanding stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a guidewire lumen into the Sullivan et al.'s catheter system in view of Dusbabek et al. in order to accommodate a guidewire therethrough for guiding the delivery system to a target site.

Regarding to slots for providing an additional flexibility, provide more flexibility to a balloon section of a balloon catheter is well known in the art. It is well known in the art to either provide the balloon section with coil or tube having slot in order to provide more flexibility to the distal end of the delivery catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ slot into the delivery catheter of Sullivan et al. in view of Dusbabek et al. in order to provide a distal end with more flexibility so that to enhance the steerability of the delivery catheter. Support well-known statement: Samson et al. 4,998,923 disclose catheter body with slot at balloon region.

Regarding to the wire insert into the wall of the catheter providing the wall region with radiopacity, it is well known in the art to reinforce the flexible region of the catheter with a wire coiling around the wall of the region and the reinforcing wire being made from radiopaque material in order to view the specific region at a desired site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a radiopaque wire into the catheter system of Sullivan et al. in view of Dusbabek et al. in order to reinforce the as well as to provide

visual. Support well-known statement: Weber (5,147,315); Peterson et al. (6,503,353) discloses catheter body including a radiopaque reinforcing wire.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

(Jackie) Tan-Uyen T. Ho Primary Examiner

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